14

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
DRYHALER		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FI00/00778	15/09/2000	17/09/1999
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant ORION CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11/04/2001	05.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Lager, J Telephone No. +49 89 2399 2957

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/FI00/00778

I. Basis of th report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-9	as originally filed				

Claims, No.:

1-13	as received on		10/11/2001	with letter of	07/11/2001

Drawings, sheets:

1/5-5/5	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,3-13
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1,3-13
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1,3-13
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Section V.

1. See Section VI and VIII below.

2. The closest prior art is represented by document D1 which discloses:

> a powder inhaler, comprising a powder container (1); an air channel (10) through which air is drawn via a mouthpiece(20); a metering member (3) equipped with a dosing recess (5), the metering member (3) being movable between a filling position in which the dosing recess (5) is filled with powder, and an inhalation position, in which the filled dosing recess (5) is brought into the air channel (10), wherein the stream of inhaled air discharges the dose of powder directly from the dosing recess (5); an actuating means (11) for the displacement of the metering member (3) between the filling and the inhalation position.

In D1 the powder container is tightly protected for external moister, see page 5, second passage and page 9, second paragraph - page 10, second paragraph.

2.1 The subject-matter of claim 1 differs therefrom in:

> a closure element connected with the actuating means, the closure element plugs the air channel around the metering member in a substantially water-proof manner, so as to protect the air channel around the metering member from moisture, when the metering member is in the filling position and opens the air channel when the metering member is in the inhalation position.

Other relevant documents are D2 (no connection between the actuator and the closure means), D3 (no closure of the air channel) and D5 (no closure of the air channel).

2.2 None of the available prior art documents suggest to provide such closure means which close off not only the metering member but also the air channel against moisture and opens the air channel upon activation of the actuating means from the filling to the inhalation position.

Claim 1, see Section VIII below, thus appears to fulfil the requirements of Article 33(2)-(3) PCT.

3. Dependent claims 3-13 define preferred embodiments of the inhaler of claim 1. These claims do therefore also fulfil the requirements of Article 33(2)-(3) PCT.

4. Claims 1, 3-13 appear therefore to fulfil the requirements of Article 33(2)-(4) PCT.

Section VI.

1. Reference is made to the following documents:

D1: WO-A-92/18188 (see in particular page 5, 2nd paragraph - page 6, line 3; page 7 first paragraph; page 8, lines 17-26; page 9, 3rd paragraph - page 10, 2nd paragraph; page 12 4th paragraph - end of page 13; and the corresponding figures).

D2: US-A-5 447 151 (see in particular column 1, line 40 - column 2, line 6; column 3, lines 19-35; column 4, line 23 - column 5, line 13; column 20, line 13 - column 22, line 25; and e.g. figure 9).

D3: EP-A-0 826 386 (see in particular column 2, lines 5-43; column 3, lines 13-23; column 5, lines 25-45; column 7, line 42 - column 9, line 10; column 11, line 28 - column 13, line 45; and the corresponding figures).

D4: US-A-5 201 308 (see abstract and figures).

D5: GB-A-2 265 552 (see abstract and figures).

D6: WO-A-93/25258 (see abstract and figures).

D7: WO-A-93/24166 (see abstract and figures).

D8: EP-A-0 166 294 (see abstract and figures).

D9: WO-A-90/12576 (see search report).

1.1 The documents D3-D8 were not cited in the international search report.

Section VII.

1. The independent claim 1 does not fulfil the requirements of Rule 6.3(b) PCT as it is nor drafted in the two part form, see Section V paragraph 2.1 above.

Section VIII.

1. The function of the closure element defined in claim 1 is not clear, Article 6 PCT taken in combination with PCT Guidelines chapter III 4.4 and 4.7. How is the closure element operated to enable it to open and close the air channel depending on the position of the metering recess?

   The assessment to novelty and inventive step drafted under Section V above is done on the basis that the actuating means is connected with the closure element, cf. claim 2.

Claims

1. A powder inhaler, comprising a

powder container (1);

an air channel (11) through which air is drawn via a mouthpiece;

a metering member (3) equipped with a dosing recess (5), the metering member (3) being movable between a filling position in which the dosing recess (5) is filled with powder, and an inhalation position, in which the filled dosing recess (5) is brought into the air channel (11), wherein the stream of inhaled air discharges the dose of powder directly from the dosing recess (5);

an actuating means (7) for the displacement of the metering member (3) between the filling and the inhalation position; and

a closure element (16) adapted to plug the air channel (11) around the metering member (3) in a substantially water-proof manner, so as to protect the air channel (11) around the metering member (3) from moisture, when the metering member (3) is in the filling position and to open the air channel (11) when the metering member (3) is in the inhalation position.

2. A powder inhaler according to claim 1, wherein the actuating means (7) communicates or is connected with the closure element (16).

3. A powder inhaler according to claim 1 or 2 comprising a first sealing means to secure the substantially water-proof plugging of the air channel (11) by the closure element (16).

4. A powder inhaler according to any of claims 1 - 3, wherein the closure element (16) is in the form of a closure plate connected to the actuating means (7).

5. A powder inhaler according to any of claims 1 - 3, wherein the closure element (16) is in the form of a pair of closure plates connected to the actuating means (7).

6. A powder inhaler according to claim 4 or 5, wherein the closure plate is equipped with a hole (17) and is slidably mounted across the air channel (11).

7. A powder inhaler according to any of claims 3 – 6, wherein the first sealing means comprises an elastic seal (18) fitted between the closure element (16) and the wall portion of the air channel (11) and means for pressing the closure element (16) tightly against the seal (18) when the inhaler is not actuated.

8. A powder inhaler according to claim 7 wherein the means for pressing the closure element (16) tightly against the seal (18) comprises a wedge-formed element (20) extending from the closure plate and adapted to contact with the pushing surface (21) as the actuator returns to its rest position.

9. A powder inhaler according to any of claims 1 - 8, wherein the metering member (3) extends into the interior of the powder container (1).

10. A powder inhaler according to claim 9, wherein the metering member (3) is in the form of an axially movable metering rod equipped with a dosing recess (5).

11. A powder inhaler according to claim 10, wherein the actuating means (7) is a depressable device cover to which the metering rod is connected.

12. A powder inhaler according to any of claims 1 – 11 comprising a second sealing means (19) for providing substantially water-proof sealing between the actuating means (7) and the inhaler body (2) while allowing the movement of the actuating means in relation to the inhaler body (2).

13. A powder inhaler of claim 12, wherein the second sealing means (19) is in the form of an elastic tube comprising a corrugated wall.

PATENT COOPERATION TREATY

PCT

10/070933

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
DRYHALER		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/FI 00/00778	15/09/2000	17/09/1999
Applicant		
ORION CORPORATION et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

[ ] as suggested by the applicant.

[X] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

[ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FI 00/00778

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 90 02576 A (FISONS PLC) 22 March 1990 (1990-03-22) page 8, line 8 -page 9, line 5 abstract ---	1-13
A	WO 92 18188 A (HUHTAMAEKI OY) 29 October 1992 (1992-10-29) the whole document ---	1-13
A	US 5 447 151 A (BRUNET MICHEL ET AL) 5 September 1995 (1995-09-05) the whole document -----	1-13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 January 2001	25. 04. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jack Hedlund

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/FI 00/00778

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9002576 A	22-03-1990	AT 90882 T	15-07-1993
		CA 1325752 A	04-01-1994
		DE 68907301 D	29-07-1993
		DK 114790 A	09-05-1990
		EP 0360463 A	28-03-1990
		EP 0388460 A	26-09-1990
		ES 2042000 T	01-12-1993
		IE 62780 B	22-02-1995
		JP 2927479 B	28-07-1999
		JP 3501225 T	22-03-1991
		PT 91669 A,B	30-03-1990
		US 5490497 A	13-02-1996
		US 5349944 A	27-09-1994
WO 9218188 A	29-10-1992	AU 650873 B	07-07-1994
		BR 9106690 A	29-06-1993
		DE 4193534 T	24-07-1997
		DE 69122388 D	31-10-1996
		DE 69122388 T	27-03-1997
		DK 533683 T	13-01-1997
		EP 0533683 A	31-03-1993
		GR 3022073 T	31-03-1997
		HK 1006813 A	19-03-1999
		KR 9602186 B	13-02-1996
		LT 929 A,B	27-03-1995
		LV 10205 A,B	20-10-1994
		NO 175136 B	30-05-1994
		RU 2093197 C	20-10-1997
		US RE35552 E	08-07-1997
		US 5295479 A	22-03-1994
US 5447151 A	05-09-1995	FR 2667509 A	10-04-1992
		WO 9205823 A	16-04-1992
		WO 9205824 A	16-04-1992
		FR 2667790 A	17-04-1992

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(25) Filing Language: English

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(30) Priority Data:
19991981 17 September 1999 (17.09.1999) FI

(71) Applicant *(for all designated States except US)*: **ORION CORPORATION** [FI/FI]; Orionintie 1, FIN-02200 Espoo (FI).

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(75) Inventor/Applicant *(for US only)*: **SEPPÄLÄ, Kari** [FI/FI]; Heinäsuontie 30 A, FIN-00430 Helsinki (FI).

(74) Agent: **ORION CORPORATION, ORION PHARMA**; Industrial Property Rights, P.O. Box 65, FIN-02101 Espoo (FI).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/21238 A2

(54) Title: MOISTURE PROTECTED POWDER INHALER

(57) Abstract: A powder inhaler comprises a powder container (1), an air channel (11), a metering member (3) equipped with a dosing recess (5), an actuating means (7) for the displacement of the metering member (3) between the filling and the inhalation position, and a closure element (16) for plugging the air channel (11) in a substantially water-proof manner when the metering member (3) is in the filling position and opening the air channel (11) when the metering member (3) is in the inhalation position. When the inhaler is not in use, the closure element (16) prevents moisture and dirt entering the sensitive parts of the device.

MOISTURE PROTECTED POWDER INHALER

Background of the invention

The present invention relates to a device for dispensing of a powdered drug preparation by inhalation. The device is in particular a multiple-dose device without propellant gas, equipped with a metering means, which dispenses doses from a powder container. The device of the invention is useful, for example, in the treatment of asthma.

The administering of a powdered drug preparation by inhalation from an inhaler is known. Multidose type powder inhalers comprising a drug container and a metering member for measuring and dispensing a unit dose are also known, for example from patent publications GB 2165159, EP 79478, and EP 166294. In these devices, a series of dosing recesses are notched into the surface of a cylindrical metering member, and the said member is disposed in a chamber of precisely the same shape. When the metering member is rotated, the dosing recesses in turn will move first to a position in alignment with the powder container for being filled and thereafter to a position in alignment with the inhalation channel, whereupon a unit dose will fall by gravity from the dosing recess into the inhalation channel. Thereafter the dose of medicament is inhaled from the inhalation channel. These devices have the drawback that they make overdosing of the medicament possible by allowing the dispensing of a plurality of doses in succession into the inhalation channel, whereby a multiple dose may be drawn by one inhalation.

Attempts have been made to solve the above-mentioned problem by using dispensing systems in which the dosing recess will not be emptied into the inhalation channel by gravity but, instead, the dose of medicament is inhaled directly from the dosing recess, such recesses having been notched into the surface of a metering member having the shape of a cylinder, a cone or a truncated cone, as disclosed in patent publications WO 92/00771 and WO 92/09322. Also in these devices, a metering member having the shape of a cylinder, a cone or a truncated cone is disposed in a chamber having precisely the same shape. When the metering member is rotated, the dosing recesses will move first to a position in alignment with the flow container for filling, and then to the inhalation channel, which is shaped so that the dosing recess will be emptied under the effect of the air flow being inhaled, and thereafter, having

rotated through a full 360°, back to a position in alignment with the flow container. Since the metering member is, for purposes of metering precision, disposed within a chamber of the same shape, and since it has to be rotated through 360°, the metering member may be prone to jamming as powder falls onto the surfaces of the device.

The above problem is at least partly avoided in multidose powder inhalers having a metering member in the form of a slide or a rod movable in its longitudinal direction. Such devices have been described e.g. in patent publications EP 758911 B, WO 97/17097, US 5,447,151, US 5,263,475, US 5,765,552 and WO 92/18188. The metering rod or slide equipped with a dosing recess may extend through the interior of the medicament container or it may slide below the orifice of the medicament container.

The above devices have a drawback that they are sensitive to external moisture, which can have a detrimental effect on the measuring accuracy of the device. If a powdered medicament is moistened, e.g. during storage or use of the device, it may form lumps which results in incomplete filling of the dosing recess. Furthermore, if the internal surfaces which are in contact with the discharging medicament powder, e.g. the metering member and the air channel, become moist, the amount of the medicament can be reduced to a fraction of the normal. The moistening may be a result of e.g. an exhalation through an inhaler. For keeping the device free of moisture or dirt, the devices usually have a protective cover, which must be opened before use.

Summary of the invention

The object of the present invention is to construct a multidose powder inhaler which avoids the above mentioned disadvantages. The sensitive parts of device of the invention are well protected against moisture and dirt, and, consequently, the device has good metering accuracy and provides complete discharge of the powdered dose into the breathing air. Furthermore, the device of the invention can be stored without protective covers or other elements, which hamper the use of the inhaler.

This is achieved by providing a device for dispensing powdered medicament by inhalation, comprising

a powder container;

an air channel through which air is drawn via a mouthpiece;

a metering member equipped with a dosing recess, the metering member being movable between a filling position in which the dosing recess is filled with powder,

and an inhalation position, in which the filled dosing recess is brought into the air channel, wherein the stream of inhaled air discharges the dose of powder directly from the dosing recess;

an actuating means for the displacement of the metering member between the filling and the inhalation position; and

a closure element for plugging the air channel in a substantially water-proof manner when the metering member is in the filling position and for opening the air channel when the metering member is in the inhalation position.

In the device of the invention the sensitive parts of the device, i.e. the parts that are in contact with the powdered medicament, such as the air channel, the metering member and the medicament container are isolated from the environment by means of the closure element. When the inhaler is not in use, the closure element plugs the air channel in a substantially water-proof manner so as to prevent moisture and dirt entering the sensitive parts of the device. Preferably the closure element comprises a pair of closure elements plugging the air channel firstly at the area of air intake and secondly at the area of air outlet. In this way the metering member with the dosing recess, the orifice of the powder container communicating with the metering member and the air channel, at least in the vicinity of the dosing area, are isolated from the environment.

An actuating means is a means operable by the user for the displacement of the metering member between the filling and the inhalation position. The actuating means may be in the form of e.g. a projection or device cover depressable by the user. It also possible that the metering member is directly operable by the user in which case the metering member is also the actuating means.

The actuating means preferably communicates or is connected with the closure element. The terms "communicate" and "connected" mean herein communicating or being connected either directly or indirectly via another element, e.g. the metering member. The movement of the actuating means by the user results to the movement of the metering member as well as the closure element.

When the actuating means is operated, e.g. depressed by the patient, for measuring a dose of powdered medicament from the container and for transferring it to the air channel for the inhalation, the air channel is opened. This may be carried out by the movement of the closure member to a position in which it no more plugs the air channel. After the inhalation the actuating means is released whereby the air channel is again closed by the closure member which moves back to the plugging position. In

this way the sensitive parts of the device are always automatically protected against moisture and dirt as well as against exhalation through the device when the device is not actuated.

The metering of the medicament dose by the metering member can be constructed in number of ways. Also the movement of the metering member by the actuating means between the first and the second positions can be achieved in number of ways.

In one preferred embodiment of the invention the metering member, which is e.g. in the form of a rod equipped with a dosing recess, extends into the interior of the medicament container. In the first position of the rod the dosing recess is inside the medicament container and receives a metered dose of the powdered medicament. In the second position the filled dosing recess is brought from the medicament container to an air channel. The metering rod is engaged with a device cover forming the actuating means that can be depressed by the patient. Alternatively, the metering rod extends through the cover and itself forms a depressable projection acting as an actuating means. Depressing of the actuating means causes metering rod to move from one position, e.g. the filling position, to another position, e.g. the inhalation position.

Alternatively, the metering member, which is e.g. in the form of a longitudinally movable metering strip, is disposed on flat surface below the medicament container as described e.g. in patent publications EP 758911 B and WO 97/17097. The metering strip equipped with a dosing recess slides between the filling and inhalation position below the bottom orifice of the medicament container. In the first position the dosing recess of the metering strip is in alignment with the bottom orifice of the medicament container whereby powder can fall through the orifice to the dosing recess. In the second position the dosing recess is brought to the air channel whereby the metered powder is discharged to the inhaled air from the dosing recess while the metering strip is in the second position. Again, as shown in EP 758911 B, the metering strip may be e.g. engaged with the device cover forming the actuating means or the metering strip extends through the device wall to form itself a depressable projection.

Alternatively, the metering member can be in the form of a rotatable metering drum equipped with one or more peripheral dosing recesses to receive in one position a dose of medicament from the powder container and to bring in another position the medicament to the air channel as described in WO 92/00771 and WO 92/09322.

Also other constructions, suitable for use in the device of the invention, of the metering member or for moving the metering member by the actuating means between the first and the second positions are conceivable to one skilled in the art.

The actuating means preferably communicates or is connected with the closure element so as to transfer the movement of the actuating means by the user to the closure element. Preferably the closure element is able to plug, in one position, the air channel both at the area of air intake and air outlet in a substantially water-proof manner so as to provide moisture protection for the metering member, the powder container as well as the air channel, at least in the vicinity of the dosing area.

The term "plugging the air channel in a substantially water-proof manner" means here that the entry of water via the air channel in an amount that would have a detrimental effect on the measuring and discharging properties of the device is prevented when the air channel is plugged. Preferably the entry of any moisture via the air channel is prevented when the air channel is plugged.

The form of the closure element depends on the dimensions and structure of the air channel. The requisite for the closure element is that it is in a form suitable to plug the air channel in a substantially water-proof manner in one position and is movable between the plugging and non-plugging positions.

In order to secure the substantially water-proof plugging of the air channel by the closure element, the contact area of the closure element and the wall portion of the air channel is preferably equipped with a sealing means. For example, a seal, e.g. an elastic seal ring, can be fitted between the closure element and the wall portion of the air channel. Preferably the sealing means also comprises a means for pressing the closure element tightly against the seal ring as the actuator returns to its rest position.

In one preferred embodiment the closure element consists of a plate equipped with a hole. The plate is connected to the actuating means, which is in the form of a depressable device cover. The plate is slidably mounted across the tubular air channel at the area of air outlet. When the inhaler is not actuated, i.e. the depressable cover is in its rest position, the plate plugs the air channel. When the inhaler is actuated, i.e. the device cover is depressed, the closure plate slides axially downwards until the hole of the plate is in alignment with the cross-section of the tubular air channel. The air channel is open and the dose ready to be inhaled. When the dose has been inhaled and the depressable cover released, the closure plate slides again to the rest position and plugs the air channel. The plugging can be secured with

an elastic seal ring and a means for pressing the closure plate tightly against the seal as described above.

Another closure plate is preferably mounted similarly at the area of air inlet, whereby the closure element consists of a pair of parallel plates both connected to the depressable cover.

In order to make the whole device substantially moisture protected when not in use, the device preferably comprises means for providing substantially water-proof sealing also between the actuating means and the inhaler body while allowing the movement of the actuating means in relation to the inhaler body. Such sealing may be e.g. in the form of an elastic tube with a central section comprising a corrugated wall. The elastic sealing tube is attached, at its one end, around the actuating means and, at its other end, around the inhaler body. The corrugated central section of the elastic sealing tube allows the longitudinal dimension of the tube to be reduced to some extent so as not to hamper the movement of the actuating means in relation to the inhaler body.

Brief description of the drawings

FIG.1 is a cross sectional side view of the device of the invention in the filling position.
FIG. 2 is a cross sectional front view of the device of FIG. 1.
FIG. 3 is a cross sectional side view of the device of the invention in the inhalation position.
FIG. 4 is a cross sectional front view of the device of FIG. 3.
FIG. 5 is a transparent front view of the actuating means and the closure element of the device of the invention.
FIG. 6 is a cross sectional side view of the actuating means and the closure element of FIG. 5.
FIG. 7 is a cross sectional side view of one embodiment of the first sealing means.
FIG. 8 is a side view of another embodiment of the first sealing means.
FIG. 9 is a front view of the structure of FIG. 8.

Detailed description of the invention

The device of the invention is further illustrated below by way of examples, with reference to Figures 1 to 9.

Figures 1 and 2 show a multidose powder inhaler with a medicament container (1) having a certain supply of powdered medicament. The container has a square cross-section and a conical end portion and is secured to an outer casing (2) by snapfastening means. Normally, the container has a supply of medicament for e.g. 200 doses. A dosing rod (3) having a flattened lower portion (4) with a dosing hole (5) is slidably mounted in the container so that it extends through the lid (6) and through the interior of the container. The bottom wall of the container has a slot adapted to receive the flattened lower portion (4) of the dosing rod (3). The upper end of the rod is fixed to a depressable cover (7) serving as an actuating means. The cover is attached to the outer casing (2) by snapfastening means e.g. such as a peripheral lip (8) which puts an upward limit on the movement of the rod. The rod is urged upwards by a spring (not shown) bearing firstly against the cover (7) and secondly against the lid (6). The downward limit on the movement of the rod is put by the projection (9) of the container.

A pair of closure plates (16) provided with a hole (17) is connected to the cover (7) as more clearly shown in Figs. 5 and 6. The function of the closure plates is to plug the air channel when the metering member is in the filling position and to open the air channel when the metering member is in the inhalation position, as will be explained later. The closure plates are slidably mounted across the air channel (11) and move in guides that cross the wall of the air channel. Fitted between the wall of the air channel (11) and the closure plate (16) is an elastic seal in the form of a ring (18).

The aperture between the cover (7) and the outer casing (2) is closed with an elastic tube (19) comprising a corrugated wall in the central section and a smooth wall in the end portions. The smooth end portions of the elastic tube attach, at one end, to the surface of the cover (7) and, at another end, to the outer casing (2). This provides a substantially water-proof sealing between the depressable cover (7) and the outer casing while allowing the necessary movement of the depressable cover in relation to the inhaler body.

The dosing rod has projections (10) for agitation of the powder in the container as the rod slides between its first and second position. This agitation effectively prevents the powder arching ("ceiling effect"), which would hinder the flow of the powder towards the dosing hole.

The outer casing (2) defines a mouthpiece through which air is drawn via an air channel (11). Below the medicament container the air channel is defined by an

element (12) containing a chamber (13) for the remnants of powder. The element (12) has an aperture (14) corresponding with the slot of the container bottom so that the flattened lower portion (4) of the dosing rod (3) is guided through the slot to the aperture (14). The air channel extends through the element (12) and through the mouthpiece as a tube. The aperture (14) leads to the chamber for remnants (13) into which remnants of powder left in the inhalation channel tends to fall by gravity. The chamber of remnants (13) is closed with a closure member in the form of a strip (15) resiliently mounted on the wall of the chamber (13). The strip (15) is engaged with the tip of the metering rod (3).

Figs 1 and 2 show the dosing rod (3) in its upper (filling) position wherein the dosing hole (5) of the dosing rod is in the medicament container for receiving powder. The flattened lower portion (4) of the rod extends slightly through the slot of the container bottom thereby preventing the flow of powder through the slot. The closure plates (16) connected to the depressable cover (7) are in the upper position to plug the air channel. The lower end of the closure plates is suitably formed such that the closure plates are pushed against the sealing ring (18) as they return to the plugging position. This is achieved by gradually increasing the thickness of the plate towards its lower end in the direction opposite to the sealing ring (18) such that the thickened portion forms a wedge-like element that abuts against the pushing surface arranged on the wall of the air channel. Details of the means for pressing the closure plates (16) tightly against the sealing ring (18) are better shown in Figures 7 – 9, which are referred to later.

Figs 3 and 4 show the dosing rod in its lower (inhalation) position wherein the cover (7) has been depressed against the spring and the dosing hole (5) has moved to the air channel (11). The tip of the flattened portion (4) of the dosing rod has entered the opening (14) and moved the strip (15) to a position where any powder on the strip (15) tends to fall by gravity to the bottom of the chamber of remnants (13). The dosing hole has stopped at the level of the slanted floor of the air channel and the dose is ready to be inhaled via mouthpiece. At the same time, the closure plates (16) connected to the cover (7) have moved in the guide slot to the position where the holes (17) are lowered to the level of the air channel (11). The diameter of the holes (17) corresponds to the diameter of the air channel (11) such that the air channel is opened for inhalation. The corrugated wall of the elastic tube (19) is in a compressed state so as to follow the movement of the depressed cover (7). The inhalation is effected while the cover is depressed. Substantially all inhaled air streams through the dosing hole and the powder is discharged into the air stream directly from the dosing hole.

After inhalation the cover (7) is released and the metering rod (3) is returned to the filling position by force exerted by the spring. At the same time, the closure plates (16) connected to the cover (7) are drawn upwards in the guide slot to the plugging position. The corrugated wall of the elastic tube (19) is now expanded so as to follow the movement of the depressed cover (7).

As the metering rod returns to the filling position, the strip (15) closes the chamber of remnants. At the same time any remnants of the powder left in the slanted portion of the air channel tend to fall through the aperture (14) to the surface of the strip (15) and upon the next return of the metering rod finally into the chamber of remnants.

Fig. 7 shows one embodiment of the means for pressing the closure plates (16) tightly against the seal (18). The closure plates (16) are in their upper position the actuator being released. Each closure plate (16) is equipped with a wedge-like element (20), which is formed by gradually increasing the thickness of the plate towards its lower end in the direction opposite to the sealing ring (18). Another similar wedge-like element (20) is positioned on the closure plate (16) at the area above the hole (17). The wedge-like elements (20) abut against the pushing surfaces (21) arranged on the wall of the air channel (11) and on the wall of the container (1), whereby the closure plates (16) are tightly pushed against the elastic seal ring (18) in a substantially water-proof manner.

Figs. 8 and 9 show another embodiment of the means for pressing the closure plates (16) tightly against the seal ring (18). In this embodiment the closure plates (16) are connected with two partially flexible bridge elements (22). The bridge elements are mounted on axles (23) extending from the closure plates (16). Pushing surfaces (24) are arranged such that upon the return of the closure plates (16) to their upper position the pushing surfaces (24) cause the bridge element (22) to be straightened slightly. Thereby the closure plates (16) are pushed tightly against the seal ring (18) in a substantially water-proof manner.

Other modifications and variations can be made to the disclosed embodiments without departing from the subject of the invention as defined in the following claims. For example, a counter could be mounted to the inhaler to count the number of pressing of the actuating means. It is considered to be routine for one skilled in the art to make such modifications to the device of the invention.

Claims

1. A powder inhaler, comprising a

powder container (1);

an air channel (11) through which air is drawn via a mouthpiece;

a metering member (3) equipped with a dosing recess (5), the metering member (3) being movable between a filling position in which the dosing recess (5) is filled with powder, and an inhalation position, in which the filled dosing recess (5) is brought into the air channel (11), wherein the stream of inhaled air discharges the dose of powder directly from the dosing recess (5);

an actuating means (7) for the displacement of the metering member (3) between the filling and the inhalation position; and

a closure element (16) for plugging the air channel (11) in a substantially water-proof manner when the metering member (3) is in the filling position and for opening the air channel (11) when the metering member (3) is in the inhalation position.

2. A powder inhaler according to claim 1, wherein the actuating means (7) communicates or is connected with the closure element (16).

3. A powder inhaler according to claim 1 or 2 comprising a first sealing means to secure the substantially water-proof plugging of the air channel (11) by the closure element (16).

4. A powder inhaler according to any of claims 1 - 3, wherein the closure element (16) is in the form of a closure plate connected to the actuating means (7).

5. A powder inhaler according to any of claims 1 - 3, wherein the closure element (16) is in the form of a pair of closure plates connected to the actuating means (7).

6. A powder inhaler according to claim 4 or 5, wherein the closure plate is equipped with a hole (17) and is slidably mounted across the air channel (11).

7. A powder inhaler according to any of claims 3 – 6, wherein the first sealing means comprises an elastic seal (18) fitted between the closure element (16) and the wall portion of the air channel (11) and means for pressing the closure element (16) tightly against the seal (18) when the inhaler is not actuated.

8. A powder inhaler according to claim 7 wherein the means for pressing the closure element (16) tightly against the seal (18) comprises a wedge-formed element (20) extending from the closure plate and adapted to contact with the pushing surface (21) as the actuator returns to its rest position.

9. A powder inhaler according to any of claims 1 - 8, wherein the metering member (3) extends into the interior of the powder container (1).

10. A powder inhaler according to claim 9, wherein the metering member (3) is in the form of an axially movable metering rod equipped with a dosing recess (5).

11. A powder inhaler according to claim 10, wherein the actuating means (7) is a depressable device cover to which the metering rod is connected.

12. A powder inhaler according to any of claims 1 – 11 comprising a second sealing means (19) for providing substantially water-proof sealing between the actuating means (7) and the inhaler body (2) while allowing the movement of the actuating means in relation to the inhaler body (2).

13. A powder inhaler of claim 12, wherein the second sealing means (19) is in the form of an elastic tube comprising a corrugated wall.

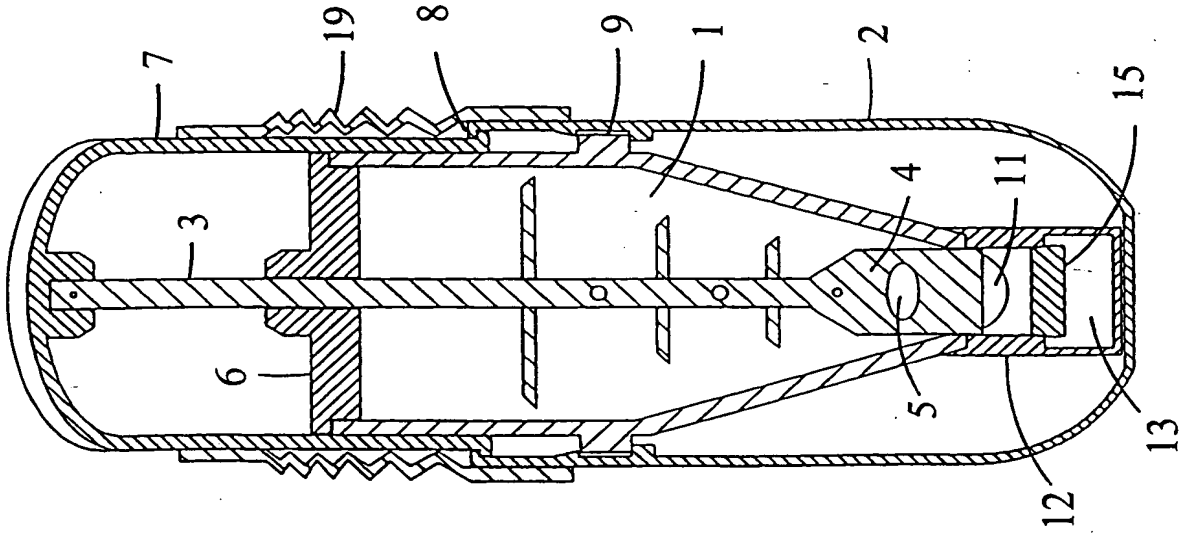
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FIG. 2

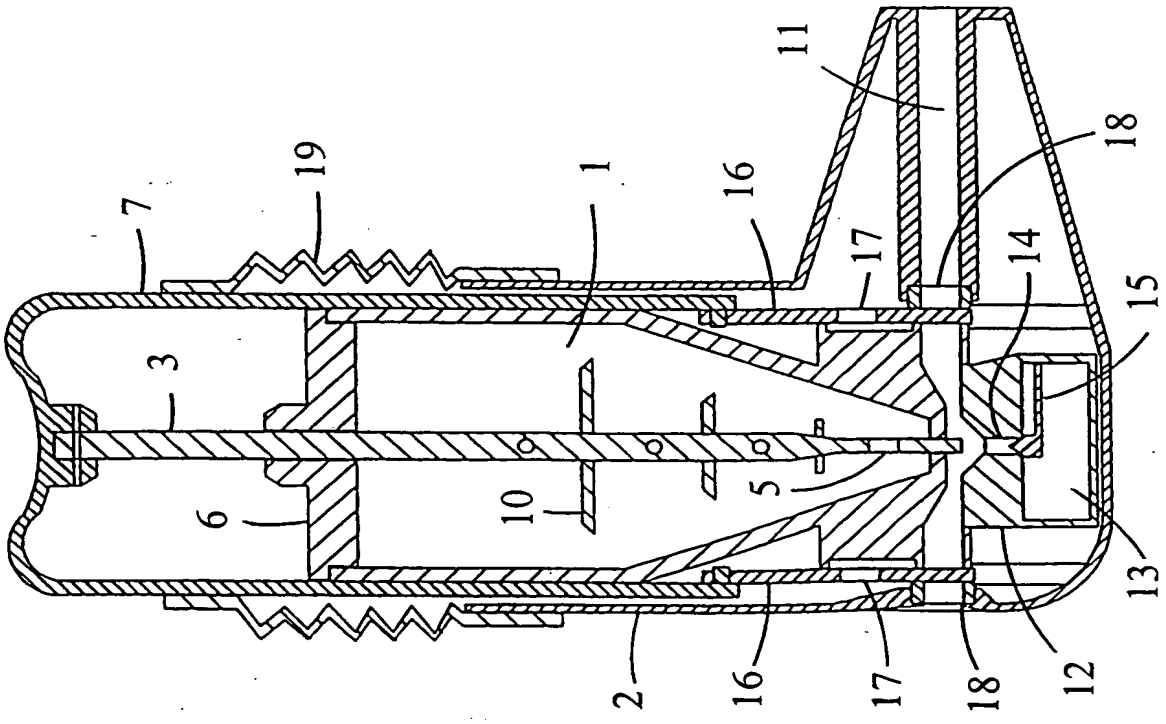
11
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FIG. 1

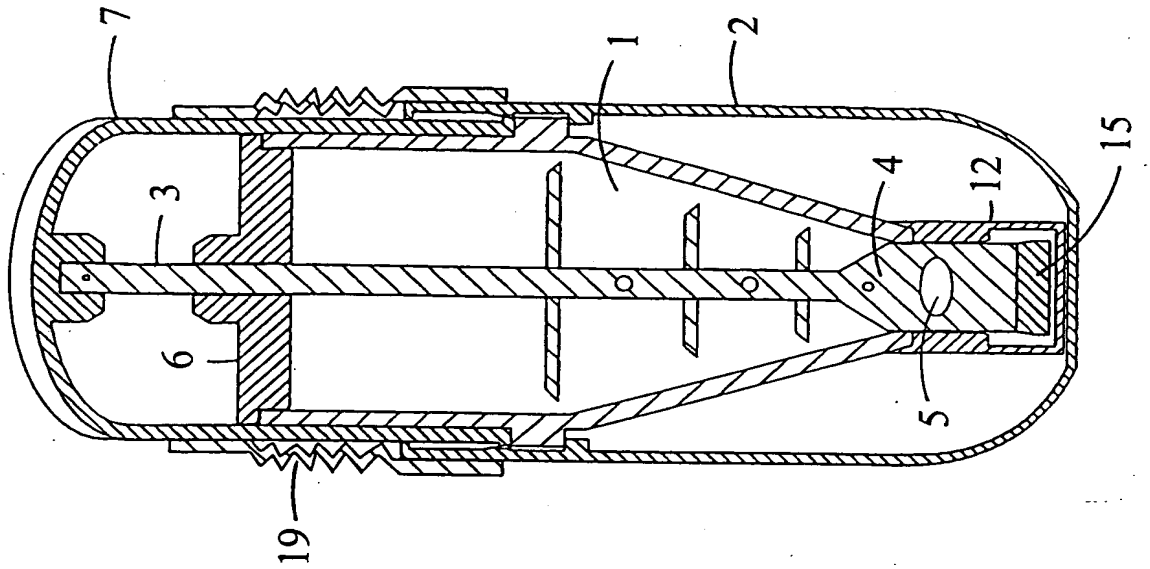

FIG. 4

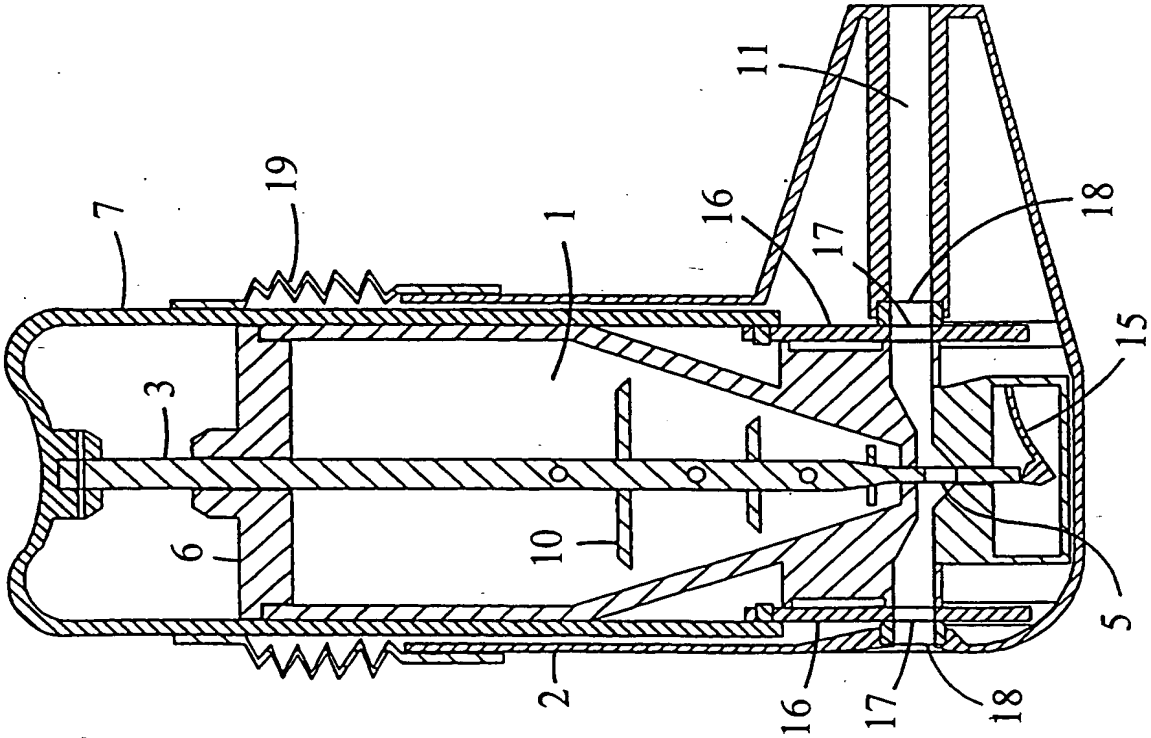

FIG. 3

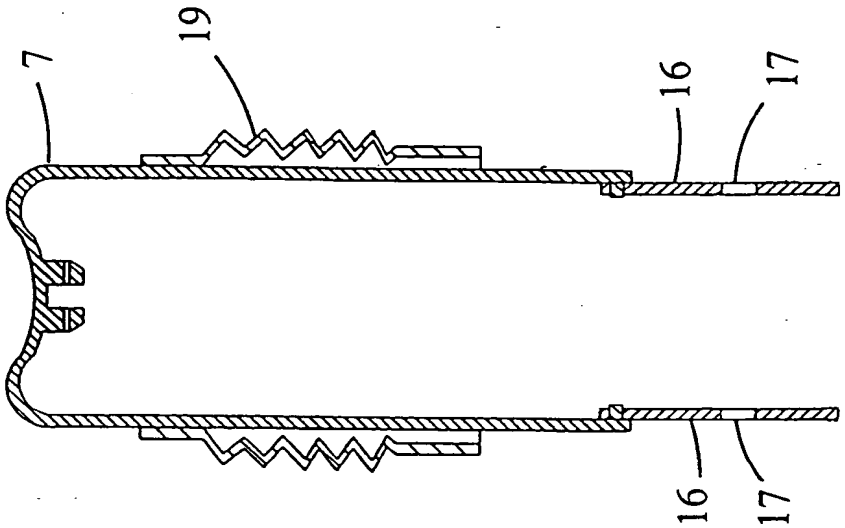

FIG. 6

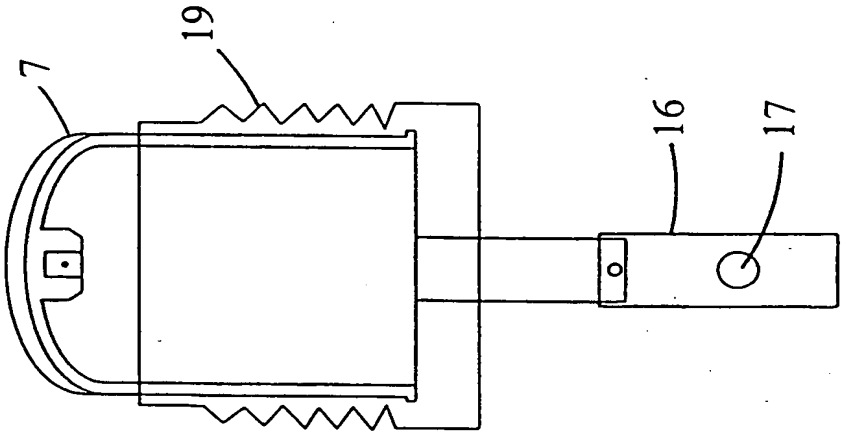

FIG. 5

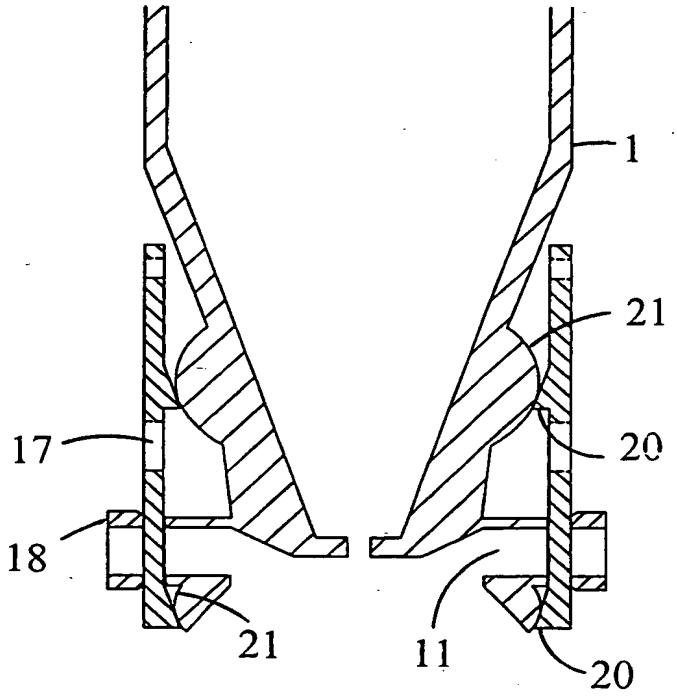

FIG. 7

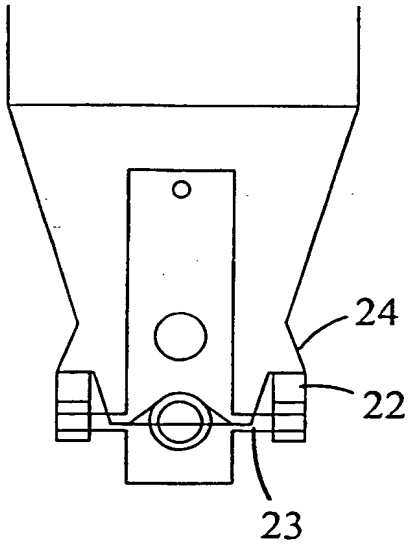

FIG. 9

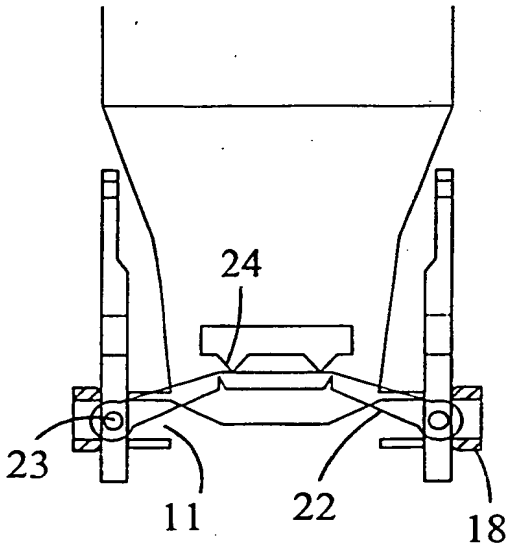

FIG. 8

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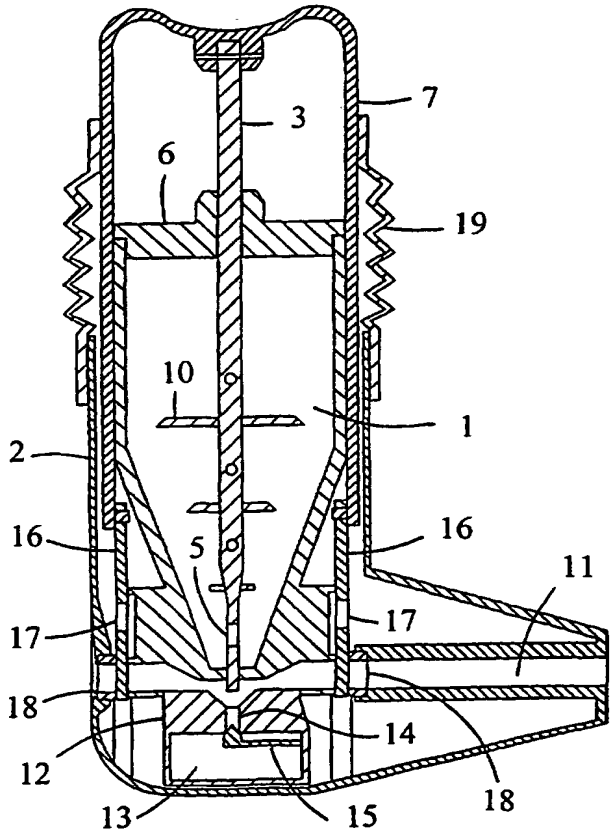
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

[Continued on next page]

(54) Title: MOISTURE PROTECTED POWDER INHALER



(57) Abstract: A powder inhaler comprises a powder container (1), an air channel (11), a metering member (3) equipped with a dosing recess (5), an actuating means (7) for the displacement of the metering member (3) between the filling and the inhalation position, and a closure element (16) for plugging the air channel (11) in a substantially water-proof manner when the metering member (3) is in the filling position and opening the air channel (11) when the metering member (3) is in the inhalation position. When the inhaler is not in use, the closure element (16) prevents moisture and dirt entering the sensitive parts of the device.

WO 01/21238 A3

patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 90 02576 A (FISONS PLC) 22 March 1990 (1990-03-22) page 8, line 8 -page 9, line 5 abstract	1-13
A	WO 92 18188 A (HUHTAMAEKI OY) 29 October 1992 (1992-10-29) the whole document	1-13
A	US 5 447 151 A (BRUNET MICHEL ET AL) 5 September 1995 (1995-09-05) the whole document	1-13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 January 2001	25. 04. 2001

Name and mailing address of the ISA	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/[redacted] 00/00778

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Claims

1. A powder inhaler, comprising a

powder container (1);

an air channel (11) through which air is drawn via a mouthpiece;

a metering member (3) equipped with a dosing recess (5), the metering member (3) being movable between a filling position in which the dosing recess (5) is filled with powder, and an inhalation position, in which the filled dosing recess (5) is brought into the air channel (11), wherein the stream of inhaled air discharges the dose of powder directly from the dosing recess (5);

an actuating means (7) for the displacement of the metering member (3) between the filling and the inhalation position; and

a closure element (16) for plugging the air channel (11) in a substantially water-proof manner when the metering member (3) is in the filling position and for opening the air channel (11) when the metering member (3) is in the inhalation position.

2. A powder inhaler according to claim 1, wherein the actuating means (7) communicates or is connected with the closure element (16).

3. A powder inhaler according to claim 1 or 2 comprising a first sealing means to secure the substantially water-proof plugging of the air channel (11) by the closure element (16).

4. A powder inhaler according to any of claims 1 - 3, wherein the closure element (16) is in the form of a closure plate connected to the actuating means (7).

5. A powder inhaler according to any of claims 1 - 3, wherein the closure element (16) is in the form of a pair of closure plates connected to the actuating means (7).

6. A powder inhaler according to claim 4 or 5, wherein the closure plate is equipped with a hole (17) and is slidably mounted across the air channel (11).

7. A powder inhaler according to any of claims 3 – 6, wherein the first sealing means comprises an elastic seal (18) fitted between the closure element (16) and the wall portion of the air channel (11) and means for pressing the closure element (16) tightly against the seal (18) when the inhaler is not actuated.

8. A powder inhaler according to claim 7 wherein the means for pressing the closure element (16) tightly against the seal (18) comprises a wedge-formed element (20) extending from the closure plate and adapted to contact with the pushing surface (21) as the actuator returns to its rest position.

9. A powder inhaler according to any of claims 1 - 8, wherein the metering member (3) extends into the interior of the powder container (1).

10. A powder inhaler according to claim 9, wherein the metering member (3) is in the form of an axially movable metering rod equipped with a dosing recess (5).

11. A powder inhaler according to claim 10, wherein the actuating means (7) is a depressable device cover to which the metering rod is connected.

12. A powder inhaler according to any of claims 1 – 11 comprising a second sealing means (19) for providing substantially water-proof sealing between the actuating means (7) and the inhaler body (2) while allowing the movement of the actuating means in relation to the inhaler body (2).

13. A powder inhaler of claim 12, wherein the second sealing means (19) is in the form of an elastic tube comprising a corrugated wall.

Annexes (amended sheets) to the Preliminary Examination Report